DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 14, 2015

AbbVie, Inc.
Katherine Wortley
Director Regulatory Affairs
1 N. Waukegan Road
North Chicago, IL 60064

Re: K142792
Trade/Device Name: AbbVie NJ
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: January 9, 2015
Received: January 12, 2015

Dear Katherine Wortley,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -
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Benjamin Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142792

Device Name: AbbVie NJ

Indications for Use:

The AbbVie NJ is intended to provide short-term enteral access for administration of medication to the small intestine. The AbbVie NJ is indicated for the administration of the medication DUOPA (carbidopa and levodopa enteral suspension).

Prescription Use _X____	AND/OR	Over-The-Counter Use ____
(21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

SUBMITTER

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Contact Person: Katherine Wortley, Ph.D., Director Regulatory Affairs
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Date Prepared: September 25, 2014

DEVICE

Name of Device:	AbbVie NJ
Common or Usual Name:	Naso-Jejunal Tube
Classification Name:	Tubes, Gastrointestinal and Accessories (21 CFR 876.5980)
Regulatory Class:	II
Product Code:	KNT

PREDICATE DEVICE

AbbVie NJ, K133129
No reference devices were used in this submission.

DEVICE DESCRIPTION

The AbbVie NJ (List Number 62903) is a 10 FR, 152 cm, naso-jejunal (NJ) tube made of white radiopaque polyurethane. The distal coiled end region and bolus tip are coated with a water activated lubricant. The AbbVie NJ includes a silicone coated stainless steel Stylet.

The kit is supplied sterile (ethylene oxide).

The AbbVie NJ is inserted through the nose and advanced into the small intestine for administration of medication in a home and/or healthcare facility environment. The Stylet is used to aid insertion and is removed once the tube is in place.

INDICATIONS FOR USE

The AbbVie NJ is intended to provide short-term enteral access for administration of medication to the small intestine. The AbbVie NJ is indicated for the administration of the medication DUOPA (carbidopa and levodopa enteral suspension).

COMPARISON OF TECHNILOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed device is identical to the predicate device (AbbVie NJ, K133129) with the exception of the proposed indication for use with DUOPA.

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the AbbVie NJ was conducted in accordance with the FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'* published May 1, 1995, *FDA Draft Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* published April 23, 2013 and International Standard

ISO 10993-1 *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process,* as recognized by FDA. A naso-jejunal tube is characterized as a "surface device" through contact with mucosal membrane. Per the standard, the contact duration can be defined as "prolonged, > 24 hours to 30 days." The stylet is used only during the tube placement procedure and contact was defined as "Limited (< 24 hours)." The battery of testing included the following:

- Cytotoxicity
- Sensitization
- Irritation (intracutaneous reactivity)
- Systemic toxicity (acute)
- Pyrogen Testing and
- Implantation.

Product Specific Performance Testing

The AbbVie NJ was assessed for conformance to standard BS EN 1615:2000 *Enteral feeding catheters and enteral giving sets for single use and their connectors – Design and testing*. An assessment of the AbbVie NJ has been completed and shown to be acceptable per ISO 80369-1:2010 *Small-bore Connectors for Liquids and Gases in Healthcare Applications- Part 1: General requirements*. AbbVie NJ has passed compatibility testing with the medication DUOPA.

Animal and Clinical Studies

No animal or clinical evaluations were performed or relied upon for the determination of substantial equivalence.

CONCLUSIONS

The proposed device, AbbVie NJ, is substantially equivalent to the predicate device as it is identical to the previously cleared predicate device (AbbVie NJ, K133129). The indication for use with DUOPA does not alter the intended use (enteral delivery of fluids) or introduce a difference that impacts safety or effectiveness of the device.